

## INTAKE PRESCRIPTION FORM

### 1. PATIENT INFORMATION

Patient's Name:		Cell Phone:	
Date of Birth:	Gender: M      F	Email Address:	
Home Address:			
City:	State:	Zip Code:	

### 2. PRESCRIBER INFORMATION

Office Contact:	Office Address:		
Email Address:	City:	State:	Zip:
Prescriber Name:	Office Name:		
Prescriber NPI #:	Office Phone:	Fax:	

### 3. PRESCRIPTION INFORMATION: Afrezza<sup>®</sup>

Package Size	NDC	Quantity & Cartridges Per Box		# of Boxes	<b>Directions For Use:</b>  · Inhale ____ units per meal · Use additional ____ units as needed  · Total Daily Units: ____  <b>Dispense Details:</b> # of Refills ____
4,8,12 Units Titration Pack (1440 units = 1 box)	47918-0902-18	1Box = 180 Cartridges (Up to 48 units/day)	2 Boxes =360 Cartridges (Up to 96 units/day)	____ Boxes	
4,8 Units Titration Pack (1080 units = 1 box)	47918-0880-18	1Box = 180 Cartridges (Up to 36 units/day)	2 Boxes =360 Cartridges (Up to 72 units/day)	____ Boxes	
8,12 Units Combo Pack (1800 units = 1 box)	47918-0898-18	1Box = 180 Cartridges (Up to 60 units/day)	2 Boxes =360 Cartridges (Up to 120 units/day)	____ Boxes	
4 Unit Cartridges (360 units = 1 box)	47918-0874-90	1Box = 90 Cartridges (Up to 12 units/day)	2Boxes = 180 Cartridges (Up to 24 units/day)	____ Boxes	
8 Unit Cartridges (720 units = 1 box)	47918-0878-90	1Box = 90 Cartridges (Up to 24 units/day)	2Boxes = 180 Cartridges (Up to 48 units/day)	____ Boxes	
12 Unit Cartridges (1080 units = 1 box)	47918-0891-90	1Box = 90 Cartridges (Up to 36 units/day)	2Boxes = 180 Cartridges (Up to 72 units/day)	____ Boxes	

### 4. PRESCRIBER SIGNATURE

<b>X</b> Prescriber Signature:	<b>X</b> Date:
--------------------------------	----------------

Please see Brief Summary of Prescribing Information for AFREZZA, including **BOXED WARNING** accompanying this form. FULL Prescribing Information including MEDICATION GUIDE and INSTRUCTIONS FOR USE (IFU) can be found on [www.afrezzahcp.com](http://www.afrezzahcp.com).



## FOR HEALTHCARE PROFESSIONALS

## INTAKE PRESCRIPTION FORM

### Indications and Usage

Afrezza® (insulin human) Inhalation Powder is a rapid acting inhaled human insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

### Limitations of Use

Not recommended for the treatment of diabetic ketoacidosis, not recommended in patients who smoke or have recently stopped smoking.

### Important Safety Information

**WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE**

- Acute bronchospasm has been observed in AFREZZA-treated patients with asthma and COPD.
- AFREZZA is contraindicated in patients with chronic lung disease such as asthma or COPD.
- Before initiating AFREZZA, perform a detailed medical history, physical examination, and spirometry (FEV<sub>1</sub>) to identify potential lung disease in all patients.

### Contraindications

AFREZZA is contraindicated: during episodes of hypoglycemia, in patients with chronic lung disease (such as asthma or chronic obstructive pulmonary disease [COPD]) because of the risk of acute bronchospasm, and in patients with hypersensitivity to regular human insulin or any of the excipients in AFREZZA.

### Warnings and Precautions

**Acute Bronchospasm:** In a study of patients with asthma whose bronchodilators were temporarily withheld for assessment, bronchoconstriction and wheezing following AFREZZA dosing was reported. Before initiating therapy, evaluate all patients with a medical history, physical examination, and spirometry (FEV<sub>1</sub>) to identify potential underlying lung disease. Do not use in patients with chronic lung disease such as asthma or COPD.

**Hypoglycemia or Hyperglycemia with Changes in Insulin Regimen:** Glucose monitoring is essential for patients receiving insulin therapy. Changes in insulin strength, manufacturer, type, or method of administration may affect glycemic control and predispose to hypoglycemia or hyperglycemia. These changes should be made under close medical supervision and the frequency of blood glucose monitoring should be increased. For patients with type 2 diabetes, dosage modifications of concomitant oral antidiabetic treatment may need to be needed.

**Hypoglycemia:** Hypoglycemia is the most common adverse reaction associated with insulins, including AFREZZA. Severe hypoglycemia can cause seizures, may be life-threatening, or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place an individual and others at risk in situations where these abilities are important (e.g., driving or operating other machinery). Hypoglycemia can happen suddenly, and symptoms may differ across patients and change over time in the same patient. Patients and caregivers should be educated to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia.

**Decline in Pulmonary Function:** AFREZZA causes a decline in lung pulmonary function over time as measured by FEV<sub>1</sub>. In clinical trials excluding patients with chronic lung disease and lasting up to 2 years, AFREZZA-treated patients experienced a small (40 mL) but greater FEV<sub>1</sub> decline than comparator-treated patients. Assess pulmonary function with spirometry at baseline, after the first 6 months of therapy and annually thereafter even in the absence of pulmonary symptoms. In patients who have a decline of  $\geq 20\%$  in FEV<sub>1</sub> from baseline, consider discontinuing AFREZZA. Consider more frequent lung function assessment in patients with pulmonary symptoms, e.g., wheezing, bronchospasm, breathing difficulties, or persistent or recurring cough. If symptoms persist, discontinue AFREZZA.

**Lung Cancer:** In clinical trials, 2 cases of lung cancer were observed in patients exposed to AFREZZA while no cases were reported for the comparators. In both cases, a prior history of heavy tobacco use was identified as a risk factor for lung cancer. Two additional cases of lung cancer (squamous cell and lung blastoma) were reported in non-smokers exposed to AFREZZA after the trial completion. These data are insufficient to determine whether AFREZZA has an effect on lung or respiratory tract tumors. In patients with active lung cancer, a prior history of lung cancer, or in patients at risk of lung cancer, consider whether the benefits of AFREZZA use outweigh this potential risk.

**Diabetic Ketoacidosis (DKA):** In clinical trials enrolling patients with type 1 diabetes, diabetic ketoacidosis (DKA) was more common in AFREZZA-treated patients (0.43%; n=13) than in comparator-treated patients (0.14%; n=3). Patients with type 1 diabetes should always use AFREZZA in combination with basal insulin. In patients at risk for DKA, such as those with an acute illness or infection, increase the frequency of glucose monitoring and consider discontinuing AFREZZA and giving insulin using an alternate route of administration.

**Hypersensitivity Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including AFREZZA. If hypersensitivity reactions occur, discontinue AFREZZA, treat per standard of care and monitor until symptoms and signs resolve.

**Hypokalemia:** All insulin products, including AFREZZA, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Closely monitor potassium levels in patients at risk of hypokalemia and treat if indicated.

**Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs):** Fluid retention, which may lead to or exacerbate heart failure, can occur with concomitant use of TZDs and insulin. Observe these patients for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the TZD should be considered.

### Drug Interactions

Certain drugs may affect glucose metabolism, increasing the risk of hypoglycemia or decreasing or increasing the blood glucose lowering effect of AFREZZA. Dose adjustment and increased frequency of blood glucose monitoring may be required. Co-administration of beta-blockers, clonidine, guanethidine, and reserpine with AFREZZA may reduce the signs and symptoms of hypoglycemia. For full list, see Prescribing Information.

### Adverse Reactions

The most common adverse reactions associated with AFREZZA are hypoglycemia, cough, and throat pain or irritation. To report SUSPECTED ADVERSE REACTIONS, contact MannKind Corporation at 1-877-323-8505 or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1-800-332-1088).

Please see Brief Summary of Prescribing Information for AFREZZA, including **BOXED WARNING** accompanying this form. FULL Prescribing Information including MEDICATION GUIDE and INSTRUCTIONS FOR USE (IFU) can be found on [www.afrezzahcp.com](http://www.afrezzahcp.com).

